## PCT

# WORLD INTELLECTUAL PROPERTY ORGANIZATION . International Bureau



#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :		(11) International Publication Number:	WO 98/36785
A61M 5/00	A1	(43) International Publication Date:	27 August 1998 (27.08.98)

(21) International Application Number: PCT/US97/02497

(22) International Filing Date: 24 February 1997 (24.02.97)

(71)(72) Applicant and Inventor: STOUDER, Albert, E., Jr. [US/US]; 318 N. West Street, Tipton, IN 46072 (US).

(74) Agents: COLE, Troy, J. et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

(81) Designated States: CA, MX, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

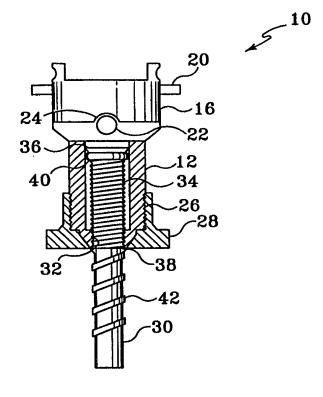
**Published** 

With international search report.

(54) Title: METHOD AND APPARATUS FOR INSERTION OF A CANNULA AND TROCAR

#### (57) Abstract

An adjustable length cannula (10) which may be longitudinally extended or retracted in order to accommodate a range of body cavity wall thicknesses. A method for inserting the cannula (10) is disclosed, in which a guiding cannula (260) is placed into the peritoneal cavity using the insufflation needle (250) as a guidewire, and a screw dilator (270) and cannula (10) are then placed into the peritoneal cavity using the guiding cannula as a guidewire. The guiding cannula (260) also allows visual inspection of the peritoneal cavity with an endoscope prior to insertion of the dilator (270)/cannula (10) in order to verify proper clearance.



### FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	ТJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
ВJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	$\mathbf{u}\mathbf{z}$	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	$\mathbf{z}\mathbf{w}$	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

# METHOD AND APPARATUS FOR INSERTION OF A CANNULA AND TROCAR

#### CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of application Serial No. 08/544,722, entitled ADJUSTABLE LENGTH CANNULA AND TROCAR, filed by the same inventor on October 18, 1995.

#### TECHNICAL FIELD OF THE INVENTION

The present invention generally relates to cannulas and trocars used to puncture tissue for the performance of laparoscopic or arthroscopic surgery and, more particularly, to a method and apparatus for insertion of a cannula and trocar.

#### BACKGROUND OF THE INVENTION

15 Prior to laparoscopic or arthroscopic surgery, a cannula is inserted through the skin to access a body cavity through the cannula tube. In order to penetrate the skin, the distal end of the cannula tube is placed against the skin and a trocar is inserted through the tube. By pressing against the proximal end of the trocar, the point of the trocar is forced through the skin until it enters the body cavity. At this time, the cannula tube in inserted through the perforation made by the trocar and the trocar is withdrawn, leaving the cannula tube as an access way into the body cavity.

10

15

25

30

35

-2-

It has been found that often a great deal of force is required to cause the trocar point to penetrate the skin and underlying tissue. When the point finally breaks through this tissue, resistance to penetration is suddenly removed, and the trocar point can suddenly penetrate to reach internal organs of the body, which may cause lacerations and other injury to the internal organs.

For this reason, when a laparoscopy is performed, a pneumoperitoneum is first performed by introducing into the peritoneal cavity 3-4 liters of CO2. The pneumoperitoneum causes rising of the front abdominal wall and separation of the internal organs thereof and in particular, if the patient is placed into a slight Trendelemburg's position, the internal organs tend to move to the upper abdominal The trocar needle must then be introduced at an region. angle of 45° in the lower periumbilical seat after sectioning of the skin (in a semi-circle around the lower edge of the navel) and the subcutis until reaching the aponeurosis. In addition, the trocar must be pushed carefully to avoid sudden deep penetration which could injure the internal organs or large vessels. despite all of these precautions, it is not always possible to avoid traumatic complications of the anatomic structures mentioned above and the complications connected with the pneumoperitoneum.

An additional problem in current laparoscopic procedures is that the thickness of abdominal tissue which must be traversed by the cannula tube varies from patient to patient. Because of this, a variety of different length cannulas are available for use in laparoscopic procedures, requiring the doctor to estimate the thickness of the abdominal tissue for the particular patient and then select a cannula having the proper length. Additionally, the present fixed length cannulas also contain no means for stabilizing the cannula against the surface of the patient's

10

15

20

-3-

body. The result is that movement of the cannula during the laparoscopic procedure can cause tissue trauma in the area of skin surrounding the cannula. The surgeon performing the laparoscopic procedure must therefore stabilize the top of the cannula tube with one hand while using the other hand to insert the laparoscopic instrument into the cannula tube. Finally, present cannula tubes protrude from the skin's surface a substantial distance, which contributes to their general instability, easily becoming entangled in tubes and other devices used in the surgical procedure.

There is therefore a need in the prior art for a cannula tube which may be used to penetrate varying thicknesses of abdominal tissue, which provides a stable interface between the cannula and the patient and which exhibits a low profile above the surface of the patient's skin. Additionally, there is a need in the prior art for a trocar which will minimize the chance of accidental trauma to the abdominal organs due to penetration of the trocar to too great a depth within the abdominal cavity. The present invention is directed toward meeting these needs.

-4-

#### SUMMARY OF THE INVENTION

The present invention relates to an adjustable length cannula which may be longitudinally extended or retracted in order to accommodate a range of body cavity wall

5 thicknesses. A method for inserting the cannula is disclosed, in which a guiding cannula is placed into the peritoneal cavity using the insufflation needle as a guidewire, and a screw dilator and cannula are then placed into the peritoneal cavity using the guiding cannula as a guidewire. The guiding cannula also allows visual inspection of the peritoneal cavity with an endoscope prior to insertion of the dilator/cannula in order to verify proper clearance.

In one form of the invention, a method for inserting a cannula through a body cavity wall and into a body cavity is disclosed, comprising the steps of: (a) inserting a guide cannula through the body cavity wall such that a distal end of the guide cannula extends into the body cavity; and (b) inserting a hollow dilator sleeved within a cannula through the body cavity wall over the guide cannula, such that a distal end of the dilator and a distal end of the cannula extend into the body cavity.

15

20

25

30

In another form of the invention, a method for inserting a cannula through a body cavity wall and into a body cavity is disclosed, comprising the steps of: (a) inserting an insufflation needle through the body cavity wall such that an opening near a distal end of the insufflation needle is within the body cavity; (b) flowing gas through the opening and into the body cavity in order to insufflate the body cavity; (c) inserting a guide cannula over the insufflation needle and through the body cavity wall such that a distal end of the guide cannula is within the body cavity; (d) withdrawing the insufflation needle from the body cavity; (e) inserting a dilator sleeved within a cannula through

5

10

15

20

-5-

he body cavity wall over the guide cannula, such that a distal end of the dilator and a distal end of the cannula extend into the body cavity; (f) withdrawing the guide cannula from the body cavity; and (g) withdrawing the dilator from the body cavity.

In another form of the invention, a method for inserting a cannula through a body cavity wall and into a body cavity is disclosed, comprising the step of: (a) sleeving a guide cannula over an insufflation needle; (b) sleeving a dilator over the guide cannula; (c) sleeving a cannula over the dilator; (d) inserting the insufflation needle through the body cavity wall such that an opening near a distal end of the insufflation needle is within the body cavity; (e) flowing gas through the opening and into the body cavity in order to insufflate the body cavity; (f) advancing the guide cannula over the insufflation needle and through the body cavity wall; (g) withdrawing the insufflation needle from the body cavity; and (h) advancing the dilator and the cannula over the guide cannula and through the body cavity wall.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a partial cross-sectional side view of a first embodiment adjustable length cannula of the present invention.
- FIG. 2 is a partial cross-sectional side view of a cap and body member of the first embodiment adjustable length cannula of the present invention.
- FIG. 3 is a bottom plan view of the body member of the first embodiment adjustable length cannula of the present invention.
  - FIG. 4 is a cross-sectional view of a collet clamp of the first embodiment adjustable length cannula of the present invention.
- FIG. 5 is a side elevational view of the collet clamp of the first embodiment adjustable length cannula of the present invention.
  - FIG. 6 is a partial cross-sectional side view of the body member and cannula member of the first embodiment adjustable length cannula of the present invention.
- FIG. 7 is a partial cross-sectional side view of a first embodiment adjustable length trocar of the present invention.
  - FIG. 8 is a partial cross-sectional side view of a second embodiment adjustable length cannula of the present invention inserted through a wall of a body cavity.
- FIG. 9 is a partial cross-sectional side view of the second embodiment adjustable length cannula of the present invention assembled with a second embodiment trocar of the present invention.
- FIG. 10 is a side elevational view of a main valve of the second embodiment adjustable length cannula of the present invention.
  - FIG. 11 is a cross-sectional side view of a body member of the second embodiment adjustable length cannula of the present invention.

- FIG. 12 is a side elevational view of a cannula member of the second embodiment adjustable length cannula of the present invention.
- FIG. 13 is a top plan view of the cannula member of FIG. 5 12.
  - FIG. 14 is a side elevational view of the second embodiment trocar of the present invention.
  - FIG. 15 is a first cross-sectional view of the trocar of FIG. 14.
- 10 FIG. 16 is a second cross-sectional view of the trocar of FIG. 14.
  - FIG. 17 is a top plan view of a slide seal of the second embodiment adjustable length cannula of the present invention.
- 15 FIG. 18 is a first side elevational view of the slide seal of FIG. 17.
  - FIG. 19 is a second side elevational view of the slide seal of FIG. 17.
- FIG. 20 is a partial cross-sectional side view of a cap of the second embodiment adjustable length cannula of the present invention.
  - FIG. 21 is a cross-sectional view of the cap of the second embodiment adjustable length cannula of the present invention.
- 25 FIG. 22 is a side elevational view of an insufflation needle.
  - FIG. 23 is a side elevational view of a guide cannula of the present invention.
- FIG. 24 is a side cross-sectional view of a third and embodiment trocar of the present invention.

-8-

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

5

10

The present invention involves the use of a single cannula which may be adjusted to any desired length within a 15 Such adjustability allows the cannula to be fixed range. used with a variety of body cavity wall thicknesses. A first embodiment of such an adjustable length cannula is illustrated in partial cross-sectional side view in FIG. 1 and is indicated generally at 10. Adjustable length cannula 20 10 comprises a body member 12 which is generally cylindrical in shape and illustrated in a partial cross-sectional view in FIGS. 1, 2 and 6. The body member 12 preferably includes either ridges or threads 14 near a top surface thereof in order to facilitate connection of a cap 16. Lying between 25 the body member 12 and the cap 16 is a suitable main seal 18, such as a silicone slit seal, which helps to provide an airtight seal around instruments which are passed through the central channel of the adjustable length cannula 10. Furthermore, the cap 16 includes a slide 20 disposed 30 therethrough, the slide 20 containing a plurality of secondary seals of various sizes in order to accommodate instruments of varying diameter which may be passed through the adjustable length cannula 10. The slide 20 is preferably constructed in accordance with the teachings of

-9-

U.S. Patent No. 5,350,362, issued to the same inventor as the present application. The body member 12 optionally includes a side port 22 which communicates between the exterior and interior of the body member 12, as is known in the art. If the optional side port 22 is present, then the cap 16 preferably includes a notch 24 in order to provide clearance for the side port 22.

Attached to the exterior of the body member 12 by means of threads 26 is a collet clamp 28. As will be explained in greater detail hereinbelow, the collet clamp 28 provides a stable platform for the adjustable length cannula in order to minimize trauma to the surrounding tissue.

10

The adjustable length cannula 10 further includes a sliding cannula member 30 which is adjustably engaged with the body member 12 by means of interaction between 15 incremental spacing members 32 on the body member 12 and incremental spacing members 34 on the cannula member 30. order to provide adjustability of the longitudinal position of the cannula member 30 within the body member 12, the incremental spacing members 32 and 34 may comprise 20 complementary threaded surfaces. Alternatively, the incremental spacing members 32 may comprise one or more raised ribs while the incremental spacing members 34 may comprise a plurality of indentations, or vise versa. 25 will therefore be appreciated by those skilled in the art that interaction between the incremental spacing members 32 and 34 allow the cannula member 30 to be extracted from or inserted into the body member 12 over a limited range in order to adjust the longitudinal length of the adjustable 30 length cannula 10. The raised lips 36 and 38 on the cannula member 30 limit the longitudinal travel of the cannula member 30 into and out of the body 12. The cannula member 30 carries an O-ring seal 40 in order to prevent passage of gases or liquids around the exterior of the cannula member 35 30.

The cannula member 30 further includes an external thread 42 around the distal section thereof, in order to facilitate insertion of the adjustable length cannula 10 and retention thereof within the body cavity during the 5 laparoscopic procedure. In operation, the relative positioning of incremental spacing members 32 and 34 is adjusted in order to lengthen or shorten the adjustable length cannula 10 to a longitudinal dimension appropriate for the patient. A trocar (not shown) is then inserted 10 through the slide seal 20, the main seal 18 and through the central channel of the cannula member 30 until the pointed distal tip of the trocar protrudes from the distal end of the cannula member 30. The adjustable length cannula 10 is then inserted through the patient's abdominal tissue (for 15 example) with a pushing and twisting motion until the annular flange at the bottom of the collet clamp 28 reaches the surface of the patient's skin. Because the contact of the collet clamp 28 with the patient's skin prevents further insertion of the adjustable length cannula 10, the danger of 20 inserting the trocar/adjustable length cannula 10 too far into the abdominal cavity, thereby potentially injuring intra-abdominal organs, is eliminated.

Furthermore, the action of the screw thread 42 as the adjustable length cannula 10 is inserted through the abdominal tissue tends to compress the abdominal wall in the area of insertion between the thread 42 and the collet clamp 28. The result is that the abdominal tissue is compressed between the outer skin and the fascia in the area of the adjustable length cannula 10, thereby providing greater stability to the adjustable length cannula 10. Furthermore, the broad surface area of the collet clamp 28 provides a stable platform to prevent excessive motion of the adjustable length cannula 10 after insertion. Not only do these features reduce tissue trauma of the abdominal wall due to decreased movement of the adjustable length cannula

25

30

35

10

15

20

25

30

35

-11-

10, but they also obviate the need for the surgeon to steady the cannula with one hand while inserting, operating and extracting instruments through its central channel. A further advantage of the adjustable length cannula 10 is that a single cannula may be used for a wide range of abdominal wall thicknesses.

Referring now to FIG. 7, there is shown a first embodiment adjustable length trocar of the present invention indicated generally at 50. Because the adjustable length cannula 10 of FIG. 1 may be adjusted to a wide range of longitudinal lengths, it is necessary to provide a trocar for use with the adjustable length cannula which may also be adjusted in longitudinal length. The trocar 50 of FIG. 7 The trocar 50 consists of a incorporates this feature. longitudinal shaft 52 terminated by a disc-shaped handle 54 at its proximal end and a pointed tip 56 at its distal end. The trocar shaft 52 is partially contained within an upper trocar housing 58 and a lower trocar housing 60. relative longitudinal positions of upper trocar housing 58 and lower trocar housing 60 are adjustable within a limited range by interaction of the threads 62 and 64.

The trocar shaft 52 includes an annular flange 66 fixedly attached thereto. Because the upper surface of the upper trocar housing 58 is held between the annular flange 66 and the trocar handle 54, the longitudinal length of the adjustable length trocar 50 (between the bottom surface of the trocar housing 50 and the distal tip 56) may be adjusted by varying the position of the upper trocar housing 58 with respect to the lower trocar housing 60. The bottom surface of the bottom trocar housing 60 rests on the upper surface of the adjustable length cannula 10, and the threads 62 and 64 are adjusted until the tip 56 of the adjustable length trocar 50 extends through the distal portion of cannula member 30. Once such positioning has been achieved, then the combination adjustable length cannula 10 and adjustable

5

10

15

20

25

30

35

-12-

length trocar 50 may be inserted into the patient as described above. The adjustable length trocar 50 may optionally be provided with an auger screw thread 68 on the pointed distal tip 56 in order to facilitate insertion of the adjustable length trocar 50 through the abdominal wall. A very controlled insertion may be achieved by twisting the adjustable length trocar 50 and the adjustable length cannula 10, thereby allowing the screw threads 68 and 42 to draw the device into the abdominal wall. This provides a much more precise insertion than the prior art devices in which the pointed trocar is simply pushed through the abdominal wall.

Referring now to FIG. 8, a second embodiment variable length cannula is illustrated in partial cross-sectional side view, and indicated generally at 100. The adjustable length cannula 100 is shown inserted through a patient's abdominal wall, comprising a skin layer, a fat layer and a fascia layer. The adjustable length cannula 100 includes a body member 112 to which is mounted a cap 116 by means of the engaged threads 114. As with the first embodiment adjustable length cannula 10, the adjustable length cannula 100 includes a slide seal 120 which allows the adjustable length cannula 100 to be sealed against laparoscopic instruments having varying diameters. Further sealing is provided by a main seal 118 which is positioned between the body member 112 and the cap 116. Situated partially within the body member 112 is a cannula member 130, incremental spacing members 132 on the body member 112 and 134 on the cannula member 130, such as complementary raised ribs and indentations or complementary screw threads, allow the longitudinal position of the cannula member 130 with respect to the body member 112 to be adjusted, thereby providing a variable length to the cannula 100. The range of motion of the cannula member 130 is limited by at least one stopper member 136 (see FIG. 13) and a lower raised lip 138.

5

10

15

20

25

30

35

rubber O-ring seal 140 provides sealing between the cannula member 130 and the body member 112. Cannula member 130 is also provided with a screw thread 142 in order to aid in insertion of the adjustable length cannula 100.

The adjustable length cannula 100 is illustrated in FIG. 8 adjusted to its shortest longitudinal length and inserted through a relatively thin abdominal wall section. be appreciated by those skilled in the art that the adjustable length cannula 100 presents a very low profile above the surface of the patient's skin owing to the fact that the body member includes a subcutaneous portion 170, which provides for the adjustability in the length of the cannula 100, lies completely below the surface of the patient's skin. The body member 112 further includes an annular flange portion 172 above the subcutaneous portion 170 which performs the same function as the collet clamp 28 of the first embodiment adjustable length cannula 10 of FIG. As illustrated in FIG. 8, the skin, fat and fascia of the abdominal wall tissue are compressed between the screw threads 142 and the annular flange 172 of the body member 112, thereby providing stability to the adjustable length cannula 100 as well as minimizing tissue trauma in the area of the cannula placement. The low external profile of the adjustable length cannula 100 further reduces accidental movement of the cannula 100, thereby further reducing tissue trauma in the area surrounding the cannula.

Referring now to FIG. 9, the adjustable length cannula 100 is shown in combination with a trocar 200. The trocar 200 includes a disc-shaped handle 202, a longitudinal shaft 204, and a pointed distal end 206. The trocar 200 includes four extensions (or fins) 208 which engage complementary notches 178 in the top of cannula member 130 (see FIG. 13) in order to allow a twisting force to be applied to the cannula member 130. The fins 208 are positioned on the trocar shaft 204 at a position where the pointed distal tip

10

15

20

25

30

35

206 will protrude from the distal end of the cannula member 130 when the fins 208 are engaged with the notches 178 on the top of the cannula member. Engagement of the fins 208 with the cannula member 130 also prevents the trocar 200 from being pushed any further from the distal end of the adjustable length cannula 100.

The adjustable length cannula 100 may be inserted into the patient's body by two different methods. One method of insertion is to insert short. In this method, the cannula member 130 is retracted completely within the body member 112 and the trocar 200 is placed within the adjustable length cannula 100. The trocar 200/cannula 100 is then inserted in the normal fashion until the annular flange 172 of the body member 112 abuts the patient's skin. point, the motion is changed to a clockwise rotation of the trocar 200, which in turn creates a clockwise rotation of the cannula member 130. Such rotation causes the cannula member 130 to be extracted from the body member 112 by action of the complementary screw threads 132 and 134. Additionally, as the cannula member 130 is extracted from the body member 112, the screw thread 142 on the cannula member 130 works its way through the abdominal tissue. rotation is continued until the tip of the cannula member 130 enters the abdominal cavity. At this point, the adjustable length cannula 100 has been inserted as far as desired by rotation of the trocar 200. By having the wide annular flange 172 of the body member 112 resting on the surface of the skin, there will be no sudden, uncontrolled penetration of the abdominal cavity as with the prior art instruments.

The second method of insertion of the adjustable length cannula 100 is to insert long. In this method, the adjustable length cannula 100 is extended to the desired length and the prior art cannula insertion method is followed until the desired penetration of the abdominal

-15-

cavity has been achieved. At this point, the body member 112 is rotated while holding the trocar 200 (and consequently the cannula member 130) stationary. Such rotation causes the body member 112 to be screwed down into the patient until the annular flange 172 rests upon the skin, thereby providing a snug fit.

Whether the adjustable length cannula 100 is inserted short or long, when the cannula is in the desired position the trocar is removed. Compression of the patient's skin and fat between the thread 142 and the annular flange surface 172 of the body member 112 establishes a relatively fixed instrument so that there is little lateral instability. This will minimize tissue trauma in the area surrounding insertion and will allow insertion of a surgical instrument through the cannula without the need to steady the cannula with a second hand.

10

15

20

25

30

35

Referring now to FIG. 10, the main seal 118 is shown in a side elevational view. The main seal 118 is preferably formed from silicone or similar materials and includes a slit therethrough in order to allow passage of the trocar 200 and surgical instruments. Referring to FIG. 11, the body member 112 is illustrated in cross-section. A protruding annular ledge 174 is clearly visible in the view of FIG. 11. The ledge 174 interacts with the stopper members 136 of the cannula member 130 in order to prevent the cannula member 130 from moving in the proximal direction beyond the ledge 174 and hitting the main seal 118. The body member 112 optionally includes a plurality of air ports 176 in order to aid in sterilization of the body member 112.

Referring to FIG. 12, the cannula member 130 is illustrated in a side elevational view. The cannula member 130 is inserted into the proximal end of the body member 112. The top stoppers 136 of the cannula member 130 will bend during insertion into the body member 112 and then snap back into position once the cannula member 130 has been

10

15

20

25

30

35

inserted into the body member 112. Thereafter, interaction between the top stoppers 136 and the ledge 174 prevent the cannula member 130 from backing out of the top of the body member 112. The cannula member 130 is illustrated in a top plan view in FIG. 13. Notches 178 formed into the top surface of the cannula 130 are clearly visible in this view. The notches 178 engage the fins 208 of the trocar 200 in order to lock the trocar 200 to the cannula 130 for rotation therewith.

Referring now to FIGS. 14-16, the trocar 200 is illustrated separated from the adjustable length cannula 100. Referring now to FIG. 17, a first embodiment of the slide seal 120 is illustrated in a top plan view. The first embodiment of the slide seal 120 includes a first seal 180 to accommodate relatively narrow instruments and a second seal 182 to accommodate relatively wide instruments. A first side elevational view of the slide seal 120 is illustrated in FIG. 18, while a second side view of the slide seal 120 is illustrated in FIG. 19. The cap 116 is illustrated in a partial cross-sectional side view in FIG. 20, and in a full cross-sectional second side view in FIG. 21. A slot 184 is formed in the cap 116 in order to accommodate the slide seal 120.

The adjustable length cannula 100 preferably measures .68 inches from the skin surface to the top of the cannula 100, 2.6 inches from the skin surface to a distal end of the cannula member 130 in a fully extended position, and 2.1 inches from the skin surface to the distal end of the cannula member 130 in a fully retracted position. Unless otherwise indicated, all of the items disclosed in the present application (except for the seals) may be constructed from plastic, stainless steel, or any other biocompatible material. Additionally, the devices may be disposable or reuseable after sterilization.

A third method for insertion of the adjustable length

5

10

15

20

25

30

35

cannula 100 utilizes the additional apparatus illustrated in FIGS. 22-24. In FIG. 22, a commonly available Verres The insufflation insufflation needle 250 is illustrated. needle 250 includes a sharp tip 252 and a longitudinal lumen (not shown) which couples the insufflation gas port 254, which may be connected to a source of insufflation gas, and the gas delivery hole 256 near the distal end of the needle Referring now to FIG. 23, there is illustrated a guide cannula 260 which includes a central longitudinal lumen (not shown) adapted to receive the insufflation needle 250 in a sliding fit. The guide cannula 260 may be made from any pliable material, such as a pliable plastic. A valve 262 is coupled to the proximal end of the guide cannula 260 in order to provide an airtight seal around any instrument which is inserted into the guide cannula 260. Valve 262 is preferably a silicone slit valve. Finally, a screw dilator 270 is illustrated in FIG. 24 in cross-section. dilator 270 is similar to the trocar 200 of FIG. 14 with the exception that the screw dilator 270 includes a central lumen 272 therein extending from the open proximal end 274 to the open distal end 276. The screw dilator 270 includes fins 278 similar to the fins 208 of the trocar 200. fins 278 are designed to engage the notches 178 of the cannula member 130 (see FIG. 13). The screw dilator 270 further includes a handle 280 at a proximal end thereof and an external thread 282 at a distal end thereof.

In the third embodiment insertion method, the insufflation needle 250 is longitudinally disposed within the central lumen of the guiding catheter 260, such that the valve 262 is sealed around the needle 250. In a preferred embodiment, the insufflation needle 250 extends from the distal end of the guiding cannula 260 by approximately 1.5 inches. The combined insufflation needle 250 and guiding cannula 260 are then longitudinally disposed within the lumen 272 of the screw dilator 270. Finally, the combined

10

15

20

25

30

35

screw dilator 270, guide cannula 260 and insufflation needle 250 are longitudinally disposed within the central lumen of the adjustable length cannula 100. Once assembled, the threads 282 of the screw dilator 270 extend from the distal end of the cannula 100, the guide cannula 260 extends from the distal end of the screw dilator 270, and the insufflation needle 250 extends from the distal end of the guide cannula 260.

Once the device has been assembled as detailed above, a supply of CO2 gas is coupled to the coupling 254 and a pneumoperitoneum is performed by inserting the insufflation needle 250 into the peritoneal cavity. Once the insufflation needle 250 has penetrated the peritoneal cavity, 3-4 liters of  $CO_2$  may be introduced into the cavity through the distal hole 256 of the insufflation The pneumoperitoneum causes rising of the front abdominal wall and separation of the internal organs thereof. Once the peritoneal cavity has been properly insufflated, the guiding cannula 260 is moved in a distal direction until a sharp increase in the CO2 gas pressure is indicated. Such a pressure increase indicates that the guiding cannula 260 has covered the hole 256 in the insufflation needle 250. The insufflation needle 250 may then be withdrawn completely from the guiding cannula 260. The valve 262 at the proximal end of the guiding cannula 260 prevents escape of gas from the peritoneal cavity.

Now that the guiding cannula 260 extends from the exterior of the patient into the peritoneal cavity, it may be used to guide the screw dilator 270 and adjustable length cannula 100 into the cavity. Using the guiding cannula 260 as a guidewire, the screw dilator 270 is inserted into the peritoneal cavity by applying pressure in a distal direction while rotating the screw dilator 270 and the cannula 100. Rotation causes the threads 282 of the screw dilator 270, as well as the threads 142 of the cannula 100 to screw through

10

15

20

25

30

35

-19-

the fascia until the cannula 100 is properly seated. Rotation of both the trocar 170 and the cannula 100 results from interaction between the trocar fins 278 and the cannula notches 178. The screw dilator 270/cannula 100 will follow the path of the guiding cannula 260. Once the cannula 100 is in place, the guiding cannula 260 and the screw dilator 270 are removed from the central lumen of the cannula 100, which is now ready for the laparoscopic procedure.

It will be appreciated by those skilled in the art that the third insertion method of the present invention allows laparoscopic surgery to be performed through a single incision which is progressively widened by sequential insertion of the insufflation needle 250, the guiding cannula 260, the screw dilator 270, and the cannula 100. Furthermore, the guiding cannula 260 may be made from a soft, pliable plastic material so that no damage will be done to the bowel if the guiding cannula 260 is scraped across it. Once the guiding cannula 260 is in place and the insufflation needle 250 has been removed, a fiber optic endoscope may be inserted into the peritoneal cavity through the guiding catheter 260 in order to visually verify that the abdominal organs are clear of the area in which the screw dilator 270 and cannula 100 will be placed. Therefore, the third insertion method of the present invention offers the significant advantage that the screw dilator 270 and cannula 100 are not inserted into the peritoneal cavity blindly. This will greatly reduce accidental injury to the abdominal organs during placement of the cannula 100.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the

5

-20-

invention are desired to be protected. Specifically, the present invention has been illustrated in use with an abdominal wall, however those skilled in the art will appreciate that the present invention may be used to access any body cavity.

-21-

#### What is claimed is:

5

15

1. An apparatus for insertion of a cannula, comprising: a screw dilator having a dilator lumen extending longitudinally therethrough and a first external thread at a distal end of the dilator;

a guide cannula disposed within the dilator lumen, the guide cannula having a guide cannula lumen extending longitudinally therethrough and a valve at an end thereof; and

an insufflation needle disposed within the guide cannula lumen, the insufflation needle having an insufflation lumen extending longitudinally therethrough, wherein the valve seals around the insufflation needle.

- 2. The apparatus of claim 1, further comprising:
- a cannula having a cannula lumen extending longitudinally therethrough a second external thread at a distal end of the cannula;

wherein the screw dilator is disposed within the cannula lumen.

- 3. The apparatus of claim 2, wherein the cannula is an adjustable length cannula.
  - 4. The apparatus of claim 1, further comprising a handle attached to a proximal end of the screw dilator.
- 5. The apparatus of claim 1, wherein the guide cannula is formed from a pliable plastic.
  - 6. The apparatus of claim 1, wherein the valve is a slit valve.

- 7. The apparatus of claim 1, further comprising a gas port attached to the insufflation needle, wherein the gas port is in fluid communication with the insufflation lumen.
- 8. The apparatus of claim 3, wherein the adjustable length cannula comprises:
  - a body member; and

10

15

20

25

a cannula member telescopically disposed with respect to the body member;

wherein the telescopic disposition of the body member and the cannula member allows an overall longitudinal length of the adjustable length cannula to be changed; and

wherein at least a portion of the telescopically disposed portions of the cannula member and the body member lie below a skin surface when the adjustable length cannula is inserted through the body cavity wall.

9. The apparatus of claim 8, further comprising: first incremental spacing members coupled to the body member; and

second incremental spacing members coupled to the cannula member, the first and second incremental spacing members being interengaged in order to provide telescoping engagement between the body member and the cannula member;

wherein at least a portion of the first and second incremental spacing members lie below a skin surface when the adjustable length cannula is inserted through the body cavity wall.

- 10. The apparatus of claim 9, wherein the first and second incremental spacing members comprise respective first and second threads.
- 11. The apparatus of claim 3, wherein the adjustable length cannula comprises:

a body member;

5

10

15

20

25

a cannula member telescopically disposed with respect to the body member; and

a clamp member adjustably engaged with the body member and including an annular flange;

wherein the annular flange abuts a skin surface when the adjustable length cannula is inserted through the body cavity wall; and

wherein the telescopic disposition of the body member and the cannula member allows an overall longitudinal length of the adjustable length cannula to be changed.

12. The apparatus of claim 11 further comprising: first incremental spacing members coupled to the body member; and

second incremental spacing members coupled to the cannula member, the first and second incremental spacing members being interengaged in order to provide telescoping engagement between the body member and the cannula member;

wherein at least a portion of the first and second incremental spacing members lie below a skin surface when the adjustable length cannula is inserted through the body cavity wall.

- 13. The apparatus of claim 12, wherein the first and second incremental spacing members comprise respective first and second threads.
  - 14. An apparatus for insertion of a cannula, comprising: an adjustable length cannula having a cannula lumen extending longitudinally therethrough;
- a screw dilator disposed within the cannula lumen, the screw dilator having a dilator lumen extending longitudinally therethrough and a first external thread at a distal end of the dilator;

-24-

a guide cannula disposed within the dilator lumen, the guide cannula having a guide cannula lumen extending longitudinally therethrough and a valve at an end thereof; and

an insufflation needle disposed within the guide cannula lumen, the insufflation needle having an insufflation lumen extending longitudinally therethrough, wherein the valve seals around the insufflation needle.

- \$15.\$ The apparatus of claim 14, wherein the adjustable \$10\$ length cannula comprises:
  - a body member; and

5

15

20

25

30

a cannula member telescopically disposed with respect to the body member;

wherein the telescopic disposition of the body member and the cannula member allows an overall longitudinal length of the adjustable length cannula to be changed; and

wherein at least a portion of the telescopically disposed portions of the cannula member and the body member lie below a skin surface when the adjustable length cannula is inserted through the body cavity wall.

16. The apparatus of claim 15, further comprising: first incremental spacing members coupled to the body member; and

second incremental spacing members coupled to the cannula member, the first and second incremental spacing members being interengaged in order to provide telescoping engagement between the body member and the cannula member;

wherein at least a portion of the first and second incremental spacing members lie below a skin surface when the adjustable length cannula is inserted through the body cavity wall.

17. The apparatus of claim 16, wherein the first and

second incremental spacing members comprise respective first and second threads.

- 18. The apparatus of claim 14, wherein the adjustable length cannula comprises:
  - a body member;

5

10

15

20

25

- a cannula member telescopically disposed with respect to the body member; and
- a clamp member adjustably engaged with the body member and including an annular flange;
- wherein the annular flange abuts a skin surface when the adjustable length cannula is inserted through the body cavity wall; and

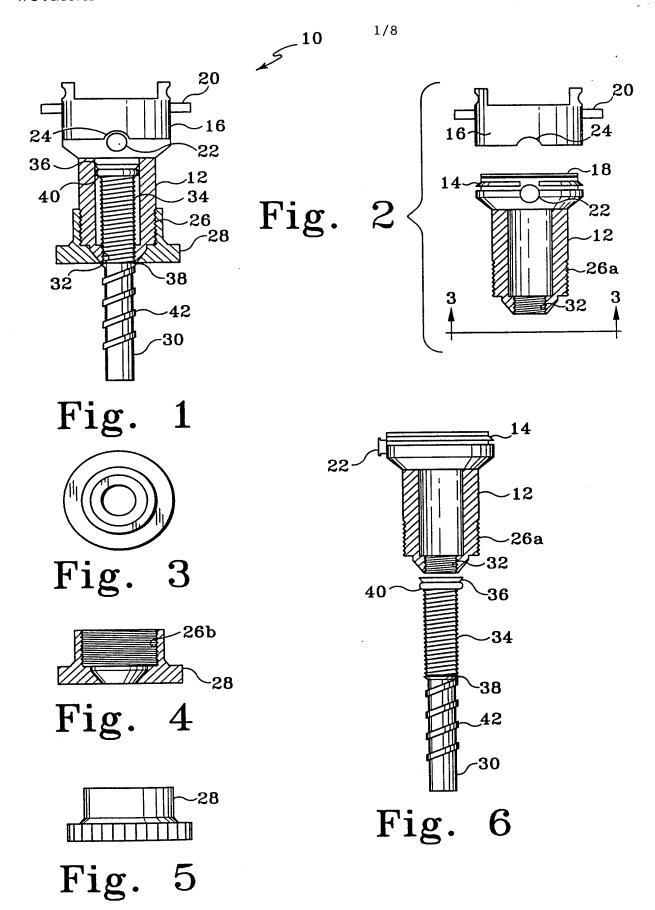
wherein the telescopic disposition of the body member and the cannula member allows an overall longitudinal length of the adjustable length cannula to be changed.

19. The apparatus of claim 15 further comprising: first incremental spacing members coupled to the body member; and

second incremental spacing members coupled to the cannula member, the first and second incremental spacing members being interengaged in order to provide telescoping engagement between the body member and the cannula member;

wherein at least a portion of the first and second incremental spacing members lie below a skin surface when the adjustable length cannula is inserted through the body cavity wall.

20. The apparatus of claim 16, wherein the first and second incremental spacing members comprise respective first and second threads.



2/8

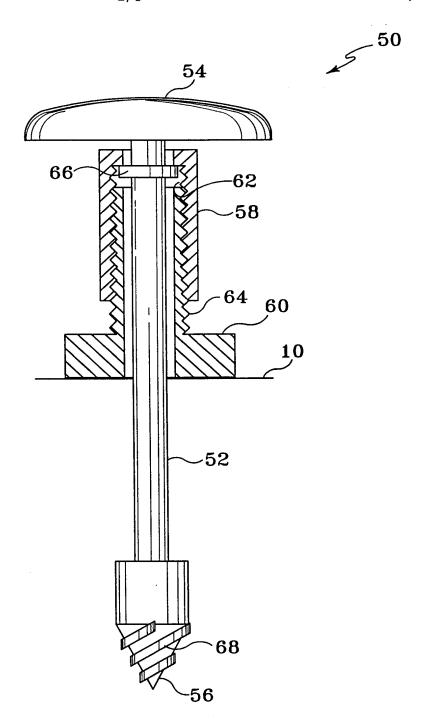


Fig. 7

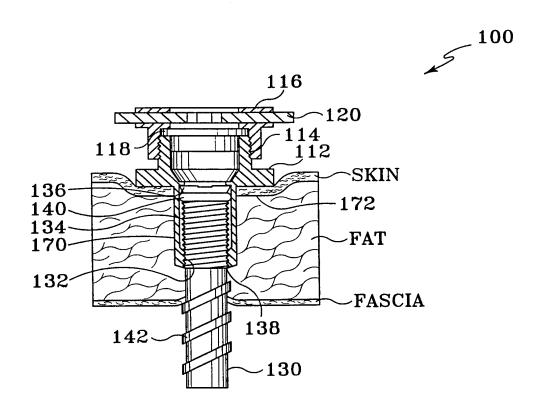


Fig. 8

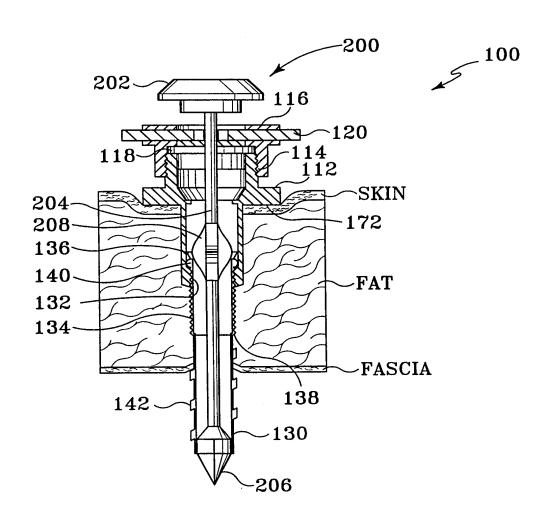
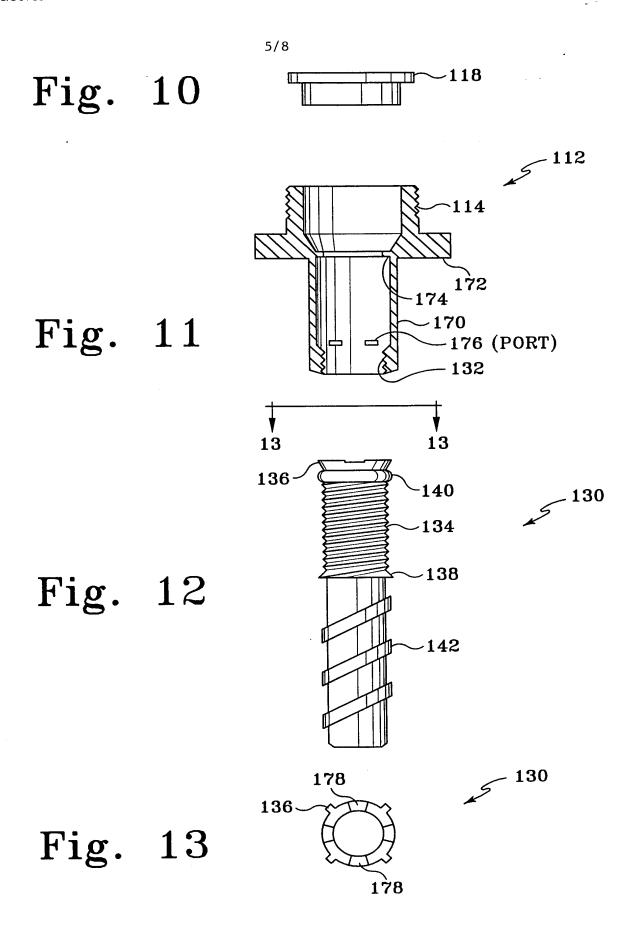


Fig. 9



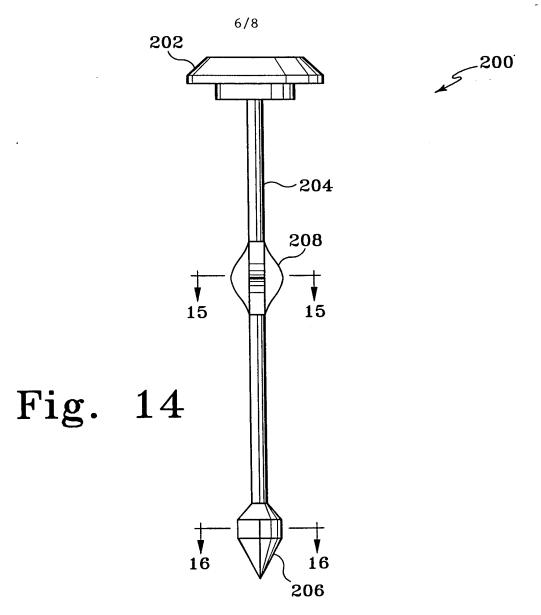
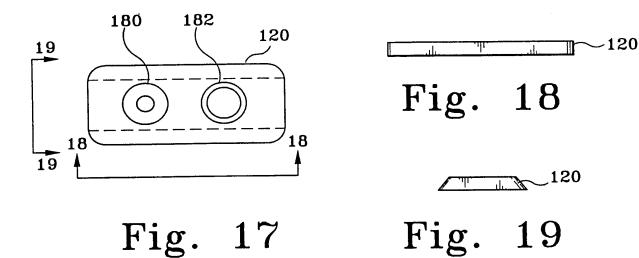
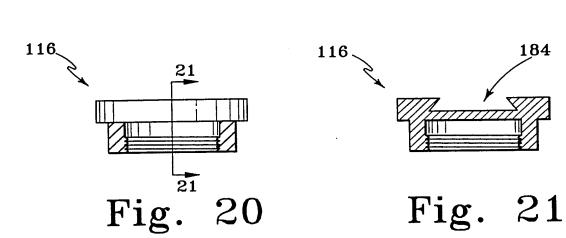




Fig. 15

Fig. 16





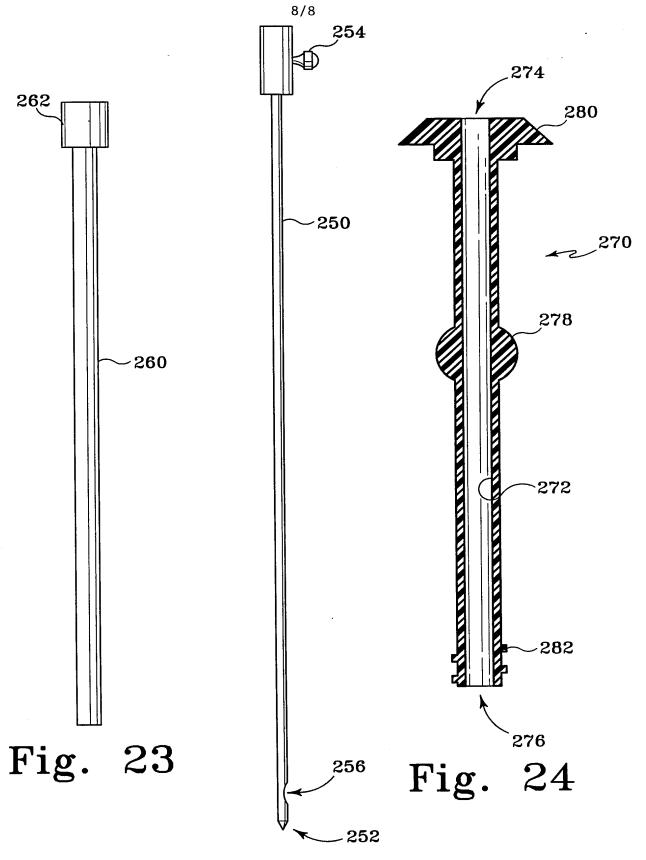


Fig. 22

SUBSTITUTE SHEET (RULE 26)

# INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/02497

A. CLA	ASSIFICATION OF SUBJECT MATTER	
IPC(6)	:A61M 5/00 :604/117	
US CL According	to International Patent Classification (IPC) or to both national classification and IPC	
B. FIEI	LDS SEARCHED	
Minimum d	documentation searched (classification system followed by classification symbols)	
U.S. :	604/117, 158, 164, 165, 167, 169, 158	
Documenta	tion searched other than minimum documentation to the extent that such documents are include	ed in the fields searched
Electronic o	data base consulted during the international search (name of data base and, where practicable	e, search terms used)
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,258,003 A (CIAGLIA et al) 02 November 1993, entire reference.	1, 4-7
Α	US 5,383,860 A (LAU) 24 January 1995, entire reference.	1-20
Α	US 5,599,305 A (HERMANN et al) 04 Feburary 1997, entire reference.	1-20
А	US 5,591,191 A (KIETURAKIS) 07 January 1997, entire reference.	1-20
А	US 5,556,411 A (TAODA et al) 17 September 1996, entire reference.	1-20
Α	US 5,312,351 A (GERRONE) 17 May 1994, entire reference.	1-20
	her documents are listed in the continuation of Box C.  See patent family annex.	
"A" do	pecial categories of cited documents:  "T" later document published after the induced and not in conflict with the applipation of the art which is not considered be of particular relevance.  In the document published after the induced principle or theory underlying the induced principle or the induced pr	cation but cited to understand the
"L" do	document of particular relevance; to considered novel or cannot be	the claimed invention cannot be dered to involve an inventive step
cit sp "O" do	ted to establish the publication date of another citation or other ecial reason (as specified)  comment referring to an oral disclosure, use, exhibition or other eans  "Y"  document of particular relevance; considered to involve an inventive combined with one or more other substitution or other substitution	re step when the document is ach documents, such combination
	ocument published prior to the international filing date but later than "&" document member of the same pater e priority date claimed	nt family
	actual completion of the international search  Date of mailing of the international search	•
29 APRII		197
Commission Box PCT	mailing address of the ISA/US oner of Patents and Trademarks  on, D.C. 20231  Adhorized of the ISA/US  LUKE YEH	Koleman
Facsimile N	/	

# INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/02497

C-+	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Category*	Chanon of document, with indication, where appropriate, of the relevant passages	Rolevant to claim No
4	US 5,009,643 A (REICH et al) 23 April 1991, entire reference.	1-20
:		